B2 cont

first and second feature points are then determined and median or average values of the timing differences are calculated.

Specific amendments to the section beginning on page 5, line 13, under the heading "Brief Description of the Drawings", have been made as follows:

Figure 1 is a schematic view of one embodiment of an implantable medical device with an endocardial lead implanted in a heart from which segments have been removed to show details;

Figure 2 is a block diagram of an implantable medical device according to one embodiment of the present system;

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Figure 3 is a flow diagram illustrating one embodiment of the present system;

[Figure 4 is] Figures 4A and 4B are a flow diagram illustrating one embodiment of the present system;

Figure 5 is an example of a far-field signal and a near-field signal from a normal rhythm complex;

Figure 6 is an example of a far-field signal and a near-field signal from an arrhythmic complex;

Figure 7 is an example of a far-field signal and a near-field signal from an arrhythmic complex;

[Figure 8 is] Figures 8A and 8B are a flow diagram illustrating one embodiment of the present system;

Figure 9 is a flow diagram illustrating one embodiment of the present system;

Figure 10 is one embodiment of a first signal and a second signal of a cardiac complex and a first signal and a second signal of a normal sinus rhythm complex, where the first signal of the cardiac complex and the first signal of the normal sinus rhythm complex are aligned;

Figure 11 is one embodiment of a first signal and a second signal of a cardiac complex and a first signal and a second signal of a normal sinus rhythm complex, where the second signal of the cardiac complex and the second signal of the normal sinus rhythm complex are aligned; and

Figure 12 is an example of a plurality of sensing channels useful in one embodiment of the

B3 cont

present system.

Specific amendments to the paragraph beginning on page 17, line 12, have been made as follows:

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Referring now to [Figure 4] Figures 4A and 4B, there is shown an alternative embodiment of the present system. At step 400, a medical device system, such as the cardiac defibrillator 100, senses cardiac signals during normal sinus rhythm using two or more simultaneous sensing channels. In one embodiment, the two or more simultaneous sensing channels include both a far-field channel and a near field channel. In providing two or more simultaneous sensing channels, cardiac complexes of the heart are being sensed from at least two different cardiac locations. So, sensed cardiac complexes include at least a first signal representative of electrical activity of the heart sensed at a first cardiac region, and a second signal representative of electrical activity of the heart is sensed at a second cardiac region. In the present embodiment, the sensed cardiac signals include cardiac electrical activation sequences (e.g., QRS-cardiac complexes) representative of a cardiac cycle.

Specific amendments to the paragraph beginning on page 19, line 24, have been made as follows:

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Alternatively, the selection criterion is a maximum deflection point of the cardiac signal, such as a maximum absolute value (*i.e.*, largest maximum or minimum value) point along either the first cardiac signal or the second cardiac signal. In an additional embodiment, the selection criterion is a point at the end of the sensed cardiac signal. In one embodiment, the end of a QRS-cardiac complex is determined by sensing the point at which the first signal returns to a baseline signal of the first signal within a predetermined time window and the point at which the second signal returns to a baseline signal of the second signal for the predetermined time window. The selection criterion can also be the [fudicial] fiducial point along the sensed cardiac signal, where the [fudicial] fiducial point is the point along the cardiac signal with the largest first derivative of the electrogram signal (*i.e.*, the point of largest slope along the sensed QRS-cardiac complex signal) Alternatively, the selection criterion is any repeatably identifiable feature along sensed cardiac signals.

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Specific amendments to the paragraph beginning on page 21, line 17, have been made as follows:

In an additional embodiment, the selection criterion is determining a point at the end of the cardiac electrical activation sequence (the QRS-cardiac complex). In one embodiment, the end of the QRS-cardiac complex is denoted by the first signal and the second signal returning to a baseline value after the occurrence of an intrinsic contraction of the heart. Figure 5 shows the point at the end of the sensed cardiac signal approximately at 512 for the first cardiac signal 500 and at 514 for the second cardiac signal 502. In a further embodiment, the selection criterion is a [fudicial] fiducial point, which is shown at approximately 516 on the second [cardia] cardiac signal 502.

Specific amendments to the paragraph beginning on page 22, line 17, have been made as follows:

Referring again to [Figure 4] Figures 4A and 4B, at step 408 the time difference between features on the cardiac complexes are determined for the cardiac complexes sensed during normal sinus rhythm. Because the cardiac complexes are being sensed at different cardiac locations (*e.g.*, the first cardiac location and the second cardiac location), there is an inherent difference in the time that the cardiac complexes will be sensed. As a result, the timing difference can be taken between corresponding features on cardiac complexes. For example, in Figure 5 there is a time difference 528 between 508 and 510 when the selection criterion is a maximum deflection point of the cardiac complex. In an additional example, there is a time difference 524 between the largest absolute peak 508 in the first cardiac signal 500 and the [fudicial] fiducial point 516 in the second cardiac signal 502.

Specific amendments to the paragraph beginning on page 25, line 7, have been made as follows:

During a tachycardia episode, the medical device system senses cardiac complexes (*e.g.*, QRS-cardiac complexes) and determines a first slope for the first signal and a second slope for the second signal. In one embodiment, both the first signal and the second signal are maximum slopes

(the [fudicial] fiducial point) for both the first signal and the second signal. The medical device system then compares the maximum slope of the first signal and the second signal of the QRS-cardiac complex to the corresponding representative slope for the first signal and the second signal. Based on this comparison, if the slope of at least one of the first signal and/or the second signal deviates from the corresponding representative slope for the first signal and the second signal by a predetermined amount, the cardiac complex is characterized as a ventricular tachycardia complex. In one embodiment, the predetermined amount is based on the percent deviation of the first signal and/or the second signal from the corresponding representative slope, where the predetermined amount is greater than or equal to 20% deviation.

Specific amendments to the paragraph beginning on page 25, line 21, have been made as follows:

Referring again to [Figure 4] Figures 4A and 4B, at 420 cardiac complexes are sensed to determined the onset of a tachycardia episode. If no tachycardia episode is sensed, the system continues to sense cardiac signals and analyzes them for the occurrence of a tachycardia episode. In one embodiment, the occurrence of a tachycardia episode is based on the cardiac rate, where a tachycardia episode is declared when the cardiac rate exceeds a predetermined threshold. In one embodiment, the predetermined threshold is a cardiac rate of between 150 and 180 beats per minute. Other systems of determining the occurrence of a tachycardia episode are known and are considered to be within the scope of the present system.

Specific amendments to the paragraph beginning on page 27, line 4, have been made as follows:

In one embodiment, the predetermined margin programmed into the implantable medical device will depend on the cardiac signal features used in determining the timing differences. For example, when timing differences being used are between the largest peak in the morphology channel signal (far-field channel) and the [fudicial] fiducial point along the rate channel signal, the predetermined margin is approximately plus or minus 10 milliseconds. In other words, if the timing

B10 difference for the tachycardia complex and the template complex differs by more than 10 milliseconds, the complex is classified as a VT complex. In this embodiment, the predetermined margin, or threshold, of 10 milliseconds is sufficient for most patients, however, the value may need to be customized for some patients.

C Specific amendments to the paragraph beginning on page 27, line 23, have been made as follows:

B11 In addition to using the same electrodes to sense the cardiac signals, the same selection criterion that were used in determining the timing template and the feature template for the normal sinus rhythm complexes are also used on the cardiac complexes sensed during the tachycardia episode. In one embodiment, the selection criterion is the maximum point of the QRS-cardiac complex. Figure 6 shows the maximum deflection point of the cardiac signal at approximately 608 for the first cardiac signal 600 and 616 for the second cardiac signal 604. In one embodiment, a time difference 624 is determined between the maximum deflection point 608 for the first cardiac signal and the maximum deflection point 616 for the second cardiac signal. In an additional embodiment, a [fudicial] fiducial point 612 is shown on the second cardiac signal 604, where the timing difference 620 between the first cardiac signal 600 and the second cardiac signal 604 is taken between the fiducial point 612 and the maximum deflection point 616 along the first cardiac signal 600.

C Specific amendments to the paragraph beginning on page 28, line 15, have been made as follows:

B12 In addition to using the same electrodes to sense the cardiac signals, the same selection criterion that were used in determining the timing template and the feature template for the normal sinus rhythm complexes are also used on the cardiac complexes sensed during the tachycardia episode. In one embodiment, the selection criterion is the maximum point of the QRS-cardiac complex. Figure 7 shows the maximum deflection point of the cardiac signal at approximately 708 for the first cardiac signal 700 and 716 for the second cardiac signal 704. In one embodiment, a time difference 724 is determined between the maximum deflection point 708 for the first cardiac signal

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B12 and the maximum deflection point 716 for the second cardiac signal. In an additional embodiment, a [fudicial] fiducial point 712 is shown on the second cardiac signal 704, where the timing difference 720 between the first cardiac signal 700 and the second cardiac signal 704 is taken between the [fudicial] fiducial point 712 and the maximum deflection point 708 along the first cardiac signal 700.

Specific amendments to the paragraph beginning on page 29, line 24, have been made as follows:

B13 Referring again to [Figure 4] Figures 4A and 4B, if the cardiac complex of the tachycardia episode is not categorized as a ventricular tachycardiac complex at 440 based on a comparison of time difference or a signal characteristic, the cardiac complex is analyzed using at least one additional classification procedure. This is necessary to rule out VT that may appear similar to NSR based on a small number of features. In one embodiment, the additional classification procedure is used to classify cardiac signals sensed during the tachycardia episode as either VT complex or non-VT complex.

Specific amendments to the paragraph beginning on page 30, line 16, have been made as follows:

B14 Referring now to [Figure 8] Figures 8A and 8B, there is shown an alternative embodiment of the present system for distinguishing VT from SVT during a tachycardia episode. In one embodiment, cardiac complexes are sensed at 400 as previously discussed. At 800, the sensed cardiac complexes are used to determine or calculate a normal sinus rhythm template, or a model, against which cardiac signals sensed during a tachycardia episode are compared. At 800, the template is determined from characteristics of the sensed cardiac signals sensed during normal sinus rhythm.

Specific amendments to the paragraph beginning on page 34, line 20, have been amended as follows:

B15 Referring now to Figure 9, there is shown an alternative embodiment of the present system. At step 900 a timing template is determined for normal sinus rhythm signals. The timing template

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can be determined as previously discussed. In the present embodiment, the timing template is determined using the time difference between the absolute maximum deflection point along a far-field signal and the [fudicial] fiducial point along a near-field signal. At 904, a feature template is also determined. The feature template can be computed as previously discussed.

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Specific amendments to the paragraph beginning on page 34, line 27, have been made as follows:

B16

Cardiac complexes are then sensed at 908 to determine when the heart has entered a tachycardia episode. If the heart enters into a tachycardia episode, the system proceeds to 912. At 912, the timing difference between the absolute maximum deflection point along a far-field signal and the [fudicial] fiducial point along a near-field signal is taken for the sensed cardiac complex. At 916, feature values are derived from the far-field signal and the near-field signal for the sensed cardiac complex. The system then proceeds to 920 where the timing difference of the cardiac complex sensed during the tachycardia episode is compared to the timing template. If the timing difference is greater than about a predetermined threshold (*e.g.*, 10 milliseconds), the cardiac complex is classified as VT complex at 924. If the timing difference is not greater than about +/- 10 milliseconds, the system then proceeds to 928 where the morphology of the far-field signal and the near-field signal are used to determined whether the cardiac complex is a VT complex or a SVT complex. Some methods useful for comparing morphologies of cardiac complexes in two or more cardiac signals are presented in U.S. Patent Application Serial No. 09/249,128, entitled "System and Method for Classifying Cardiac Complexes " which is filed on the same day as the instant U.S. Patent application and that is hereby incorporated by reference in its entirety.

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Docket No. 00279.084US2 CPI Ref. No. 99-030A

Clean Version of the Amended Specification Paragraphs

SYSTEM AND METHOD FOR ARRHYTHMIA DISCRIMINATION
Applicant: William Hsu et al.
Serial No.: 10/014,933

On page 1, please replace the paragraph under the heading "Cross-Reference to Related Applications," with the following:

This application is a continuation of U.S. Patent Application No. 09/248,800, filed on February 12, 1999, now issued as U.S. Patent No. 6,308,095, the specification of which is incorporated herein by reference.

Please replace the paragraph beginning on page 3, line 25, with the following:

In one embodiment, the first feature point along the first cardiac signal and the second feature point along the second cardiac signal are determined from morphological features along the cardiac signals. In one embodiment, the morphological features along the cardiac signals can be any combination of maximum deflection points of the cardiac signals, the beginning or ending of cardiac signals, and/or fiducial points along the cardiac signals. Timing differences between the first and second feature points are then determined and median or average values of the timing differences are calculated.

Please replace the section beginning on page 5, line 13, under the heading "Brief Description of the Drawings", with the following:

Figure 1 is a schematic view of one embodiment of an implantable medical device with an endocardial lead implanted in a heart from which segments have been removed to show details;

Figure 2 is a block diagram of an implantable medical device according to one embodiment of the present system;

Figure 3 is a flow diagram illustrating one embodiment of the present system;

Figures 4A and 4B are a flow diagram illustrating one embodiment of the present system;

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Figure 5 is an example of a far-field signal and a near-field signal from a normal rhythm complex;

Figure 6 is an example of a far-field signal and a near-field signal from an arrhythmic complex;

Figure 7 is an example of a far-field signal and a near-field signal from an arrhythmic complex;

Figures 8A and 8B are a flow diagram illustrating one embodiment of the present system;

Figure 9 is a flow diagram illustrating one embodiment of the present system;

Figure 10 is one embodiment of a first signal and a second signal of a cardiac complex and a first signal and a second signal of a normal sinus rhythm complex, where the first signal of the cardiac complex and the first signal of the normal sinus rhythm complex are aligned;

Figure 11 is one embodiment of a first signal and a second signal of a cardiac complex and a first signal and a second signal of a normal sinus rhythm complex, where the second signal of the cardiac complex and the second signal of the normal sinus rhythm complex are aligned; and

Figure 12 is an example of a plurality of sensing channels useful in one embodiment of the present system.

Please replace the paragraph beginning on page 17, line 12, with the following:

Referring now to Figures 4A and 4B, there is shown an alternative embodiment of the present system. At step 400, a medical device system, such as the cardiac defibrillator 100, senses cardiac signals during normal sinus rhythm using two or more simultaneous sensing channels. In one embodiment, the two or more simultaneous sensing channels include both a far-field channel and a near field channel. In providing two or more simultaneous sensing channels, cardiac complexes of the heart are being sensed from at least two different cardiac locations. So, sensed cardiac complexes include at least a first signal representative of electrical activity of the

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heart sensed at a first cardiac region, and a second signal representative of electrical activity of the heart is sensed at a second cardiac region. In the present embodiment, the sensed cardiac signals include cardiac electrical activation sequences (e.g., QRS-cardiac complexes) representative of a cardiac cycle.

Please replace the paragraph beginning on page 19, line 24, with the following:

Alternatively, the selection criterion is a maximum deflection point of the cardiac signal, such as a maximum absolute value (*i.e.*, largest maximum or minimum value) point along either the first cardiac signal or the second cardiac signal. In an additional embodiment, the selection criterion is a point at the end of the sensed cardiac signal. In one embodiment, the end of a QRS-cardiac complex is determined by sensing the point at which the first signal returns to a baseline signal of the first signal within a predetermined time window and the point at which the second signal returns to a baseline signal of the second signal for the predetermined time window. The selection criterion can also be the fiducial point along the sensed cardiac signal, where the fiducial point is the point along the cardiac signal with the largest first derivative of the electrogram signal (*i.e.*, the point of largest slope along the sensed QRS-cardiac complex signal) Alternatively, the selection criterion is any repeatably identifiable feature along sensed cardiac signals.

Please replace the paragraph beginning on page 21, line 17, with the following:

In an additional embodiment, the selection criterion is determining a point at the end of the cardiac electrical activation sequence (the QRS-cardiac complex). In one embodiment, the end of the QRS-cardiac complex is denoted by the first signal and the second signal returning to a baseline value after the occurrence of an intrinsic contraction of the heart. Figure 5 shows the point at the end of the sensed cardiac signal approximately at 512 for the first cardiac signal 500 and at 514 for the second cardiac signal 502. In a further embodiment, the selection criterion is a fiducial point, which is shown at approximately 516 on the second cardiac signal 502.

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Please replace the paragraph beginning on page 22, line 17, with the following:

Referring again to Figures 4A and 4B, at step 408 the time difference between features on the cardiac complexes are determined for the cardiac complexes sensed during normal sinus rhythm. Because the cardiac complexes are being sensed at different cardiac locations (*e.g.*, the first cardiac location and the second cardiac location), there is an inherent difference in the time that the cardiac complexes will be sensed. As a result, the timing difference can be taken between corresponding features on cardiac complexes. For example, in Figure 5 there is a time difference 528 between 508 and 510 when the selection criterion is a maximum deflection point of the cardiac complex. In an additional example, there is a time difference 524 between the largest absolute peak 508 in the first cardiac signal 500 and the fiducial point 516 in the second cardiac signal 502.

Please replace the paragraph beginning on page 25, line 7, with the following:

During a tachycardia episode, the medical device system senses cardiac complexes (*e.g.*, QRS-cardiac complexes) and determines a first slope for the first signal and a second slope for the second signal. In one embodiment, both the first signal and the second signal are maximum slopes (the fiducial point) for both the first signal and the second signal. The medical device system then compares the maximum slope of the first signal and the second signal of the QRS-cardiac complex to the corresponding representative slope for the first signal and the second signal. Based on this comparison, if the slope of at least one of the first signal and/or the second signal deviates from the corresponding representative slope for the first signal and the second signal by a predetermined amount, the cardiac complex is characterized as a ventricular tachycardia complex. In one embodiment, the predetermined amount is based on the percent deviation of the first signal and/or the second signal from the corresponding representative slope, where the predetermined amount is greater than or equal to 20% deviation.

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Please replace the paragraph beginning on page 25, line 21, with the following:

Referring again to Figures 4A and 4B, at 420 cardiac complexes are sensed to determined the onset of a tachycardia episode. If no tachycardia episode is sensed, the system continues to sense cardiac signals and analyzes them for the occurrence of a tachycardia episode. In one embodiment, the occurrence of a tachycardia episode is based on the cardiac rate, where a tachycardia episode is declared when the cardiac rate exceeds a predetermined threshold. In one embodiment, the predetermined threshold is a cardiac rate of between 150 and 180 beats per minute. Other systems of determining the occurrence of a tachycardia episode are known and are considered to be within the scope of the present system.

Please replace the paragraph beginning on page 27, line 4, with the following:

In one embodiment, the predetermined margin programmed into the implantable medical device will depend on the cardiac signal features used in determining the timing differences. For example, when timing differences being used are between the largest peak in the morphology channel signal (far-field channel) and the fiducial point along the rate channel signal, the predetermined margin is approximately plus or minus 10 milliseconds. In other words, if the timing difference for the tachycardia complex and the template complex differs by more than 10 milliseconds, the complex is classified as a VT complex. In this embodiment, the predetermined margin, or threshold, of 10 milliseconds is sufficient for most patients, however, the value may need to be customized for some patients.

Please replace the paragraph beginning on page 27, line 23, with the following:

In addition to using the same electrodes to sense the cardiac signals, the same selection criterion that were used in determining the timing template and the feature template for the normal sinus rhythm complexes are also used on the cardiac complexes sensed during the tachycardia episode. In one embodiment, the selection criterion is the maximum point of the QRS-cardiac complex. Figure 6 shows the maximum deflection point of the cardiac signal at

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approximately 608 for the first cardiac signal 600 and 616 for the second cardiac signal 604. In one embodiment, a time difference 624 is determined between the maximum deflection point 608 for the first cardiac signal and the maximum deflection point 616 for the second cardiac signal. In an additional embodiment, a fiducial point 612 is shown on the second cardiac signal 604, where the timing difference 620 between the first cardiac signal 600 and the second cardiac signal 604 is taken between the fiducial point 612 and the maximum deflection point 616 along the first cardiac signal 600.

Please replace the paragraph beginning on page 28, line 15, with the following:

In addition to using the same electrodes to sense the cardiac signals, the same selection criterion that were used in determining the timing template and the feature template for the normal sinus rhythm complexes are also used on the cardiac complexes sensed during the tachycardia episode. In one embodiment, the selection criterion is the maximum point of the QRS-cardiac complex. Figure 7 shows the maximum deflection point of the cardiac signal at approximately 708 for the first cardiac signal 700 and 716 for the second cardiac signal 704. In one embodiment, a time difference 724 is determined between the maximum deflection point 708 for the first cardiac signal and the maximum deflection point 716 for the second cardiac signal. In an additional embodiment, a fiducial point 712 is shown on the second cardiac signal 704, where the timing difference 720 between the first cardiac signal 700 and the second cardiac signal 704 is taken between the fiducial point 712 and the maximum deflection point 708 along the first cardiac signal 700.

Please replace the paragraph beginning on page 29, line 24, with the following:

Referring again to Figures 4A and 4B, if the cardiac complex of the tachycardia episode is not categorized as a ventricular tachycardiac complex at 440 based on a comparison of time difference or a signal characteristic, the cardiac complex is analyzed using at least one additional classification procedure. This is necessary to rule out VT that may appear similar to NSR based

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on a small number of features. In one embodiment, the additional classification procedure is used to classify cardiac signals sensed during the tachycardia episode as either VT complex or non-VT complex.

Please replace the paragraph beginning on page 30, line 16, with the following:

Referring now to Figures 8A and 8B, there is shown an alternative embodiment of the present system for distinguishing VT from SVT during a tachycardia episode. In one embodiment, cardiac complexes are sensed at 400 as previously discussed. At 800, the sensed cardiac complexes are used to determine or calculate a normal sinus rhythm template, or a model, against which cardiac signals sensed during a tachycardia episode are compared. At 800, the template is determined from characteristics of the sensed cardiac signals sensed during normal sinus rhythm.

Please replace the paragraph beginning on page 34, line 20, with the following:

Referring now to Figure 9, there is shown an alternative embodiment of the present system. At step 900 a timing template is determined for normal sinus rhythm signals. The timing template can be determined as previously discussed. In the present embodiment, the timing template is determined using the time difference between the absolute maximum deflection point along a far-field signal and the fiducial point along a near-field signal. At 904, a feature template is also determined. The feature template can be computed as previously discussed.

Please replace the paragraph beginning on page 34, line 27, with the following:

Cardiac complexes are then sensed at 908 to determine when the heart has entered a tachycardia episode. If the heart enters into a tachycardia episode, the system proceeds to 912. At 912, the timing difference between the absolute maximum deflection point along a far-field signal and the fiducial point along a near-field signal is taken for the sensed cardiac complex. At 916, feature values are derived from the far-field signal and the near-field signal for the sensed

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cardiac complex. The system then proceeds to 920 where the timing difference of the cardiac complex sensed during the tachycardia episode is compared to the timing template. If the timing difference is greater than about a predetermined threshold (*e.g.,* 10 milliseconds), the cardiac complex is classified as VT complex at 924. If the timing difference is not greater than about +/- 10 milliseconds, the system then proceeds to 928 where the morphology of the far-field signal and the near-field signal are used to determined whether the cardiac complex is a VT complex or a SVT complex. Some methods useful for comparing morphologies of cardiac complexes in two or more cardiac signals are presented in U.S. Patent Application Serial No. 09/249,128, entitled "System and Method for Classifying Cardiac Complexes " which is filed on the same day as the instant U.S. Patent application and that is hereby incorporated by reference in its entirety.

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